

ko 90838

**Appendix J**  
**510(k) Summary of Substantial Equivalence**

JUL 20 2009

**510k Summary of Safety and Effectiveness**

**Company Name:** Axon Systems, Inc.  
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Hauppauge, NY 11788

**Contact:** Howard Bailin  
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**Summary Date** February 26, 2009

**Proprietary Name:** XPAK II  
XPAK

**Common Name:** Nerve Stimulator/Locator

**Classification:** Class II (Performance Standards)  
Number: 874.1820 Nerve Stimulator/Locator  
Procode: ETN

**Predicate Devices**  
Manufacturer: Medtronic Xomed  
Trade Name: Stimulus Dissection Instruments  
FDA number: K031003

Manufacturer: Axon Systems, Inc  
Trade Name: Disposable Stimulator Probes  
FDA number: K062996

Manufacturer: Nuvasive  
Trade Name: Surgical Nerve Stimulator/Locator  
FDA number: K002677

**Appendix J**  
**510(k) Summary of Substantial Equivalence**

**Device Description**

Axon Systems' Stimulus Dissection Instruments are disposable (for "Single Use Only"), sterile devices used for tissue dissection and stimulation of spinal nerve roots for location and identification during surgery.

These instruments consists of probes of differing shapes and sizes with biocompatible electrical insulation applied to select portions, and proximal connectors provided to attach the instruments to a monopolar stimulator. The distal surfaces of the instruments are non-insulated stainless steel to provide for probing and tissue stimulation. The probes are a protected pin design and meet the requirements of IEC 60601-1:1988 / A1:1991 / A2:1995 Clause 56.3(c) per 21 CFR 898.12

The instruments consist of needles, probes and dilators (expanding set of cannulas) designed to provide physicians with the ability to perform tissue dissection and stimulation intraoperatively.

The designs of the proposed Stimulus Dissection accessories are similar to Class I exempt surgical instruments such as those described in 21 CFR 888.4540 Orthopedic Manual Surgical Instrument. The instruments consists of stainless steel and aluminum alloy needles, probes and dilators with biocompatible electrical insulation applied to selected portions, proximal electrical connectors to attach the instruments to a monopolar electrical stimulator and in some cases, a proximal ABS handle. The distal surfaces of the instruments are non-insulated and provide for manual dissection / resection / probing and tissue stimulation.

**Intended Use**

These instruments are intended to be used for pedicle preparation or access to the vertebral body. The instruments are used for screw placement in open and minimally invasive procedures to reduce the risk of nerve root injury and deficits from misplaced screws by providing early warning of pedicle breach.

**Technological Characteristics**

These Stimulus Dissection Instruments consists of needles, probes and dilators of differing shapes and sizes with biocompatible electrical insulation applied to select portions, and proximal connectors provided to attach the instruments to a monopolar stimulator. The distal surfaces of the instruments are non-insulated stainless steel to provide for probing and tissue stimulation. The connector is specifically designed so that it cannot be plugged into AC power outlet. The Stimulus Dissection Instruments are supplied in dual barrier sterile trays. Materials used are the same as in the predicate devices.

**Conclusions**

Axon Systems' Stimulus Dissection Instruments are substantially equivalent to the predicate devices. No new questions of safety or effectiveness are raised or evident.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
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Axon Systems, Inc.  
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Hauppauge, NY 11788

JUL 20 2009

Re: K090838

Trade Name: Axon Systems, Inc. Stimulus/dissection instruments  
Regulation Number: 21 CFR § 874.1820  
Regulation Name: Surgical Nerve Stimulator/Locator  
Regulatory Class: Class II  
Product Code: ETN  
Dated: May 27, 2009  
Received: June 9, 2009

Dear Mr. Bailin:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

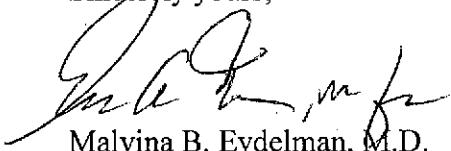
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/cdrh/mdr/> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Malvina B. Eydelman, M.D.  
Director  
Division of Ophthalmic, Neurological  
and Ear, Nose and Throat Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health

Enclosure

## Indications for Use

510(k) Number: K090838

Device Name: Axon Systems, Inc. Stimulus/dissection instruments

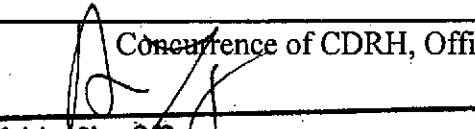
### Indications For Use:

These instruments are indicated for tissue dissection and stimulation of spinal nerve roots for identification and location during surgery.

Prescription Use X  
(Part 21 CFR 801 Subpart D)

AND/OR  
Over-The-Counter Use \_\_\_\_\_  
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

  
Concurrence of CDRH, Office of Device Evaluation (ODE)  
  
Division Sign-Off  
Division of Ophthalmic, Neurological and Ear,  
Nose and Throat Devices

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